

Application of: Judith A. Varner et al.

Serial No.: 10/518,181

371 Date: 09/09/2005

Group No.: 163 Examiner: Ng

1633 Nguyen, Q.

Entitled:

Methods for Inhibiting Angiogenesis, Cell Migration, Cell Adhesion,

and Cell Survival

INFORMATION DISCLOSURE STATEMENT

MS Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria YA 2313-1450.

Dated: September 5, 2007

By: _

Cliff Cannon-Cin

Dear Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application.

The following citations are referred to in the body of the Specification:

- Abou-Samra et al., "Expression cloning of a common receptor for parathyroid hormone
 and parathyroid hormone-related peptide from rat osteoblast-like cells: a single receptor
 stimulates intracellular accumulation of both cAMP and inositol trisphosphates and
 increases intracellular free calcium," Proc Natl Acad Sci USA, 89: 2732-2736 (1992);
- Amizuka et al., "Parathyroid hormone-related peptide-depleted mice show abnormal epiphyseal cartilage development and altered endochondral bone formation," J Cell Biol, 126: 1611-1623 (1994);

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- Ausprunk et al., "Vascularization of normal and neoplastic tissues grafted to the chick chorioallantois. Role of host and preexisting graft blood vessels," Amer J Pathol, 79:597-628 (1975);
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- Brooks et al., "Requirement of vascular integrin alpha-v/beta-3 for angiogenesis,"
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- Bukoski *et al.*, "Vascular actions of the calcium-regulating hormones," Semin Nephrol, 15: 536-549 (1995) abstract;
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- Christofidou-Solomidou *et al.*, "Expression and function of endothelial cell alpha-v integrin receptors in wound-induced human angiogenesis in human skin/SCID mice chimeras," Am J Pathol, 151: 975-983 (1997);
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- Clegg *et al.*, "Inhibition of intracellular cAMP-dependent protein kinase using mutant genes of the regulatory type I subunit," J Biol Chem, 262: 13111-13119 (1987);
- Dormond *et al.*, "NSAIDs inhibit alpha-v/beta-3 integrin-mediated and Cdc42/Rac-dependent endothelial-cell spreading, migration and angiogenesis," Nat Med, 7: 1041-1047 (2001);

- Drake *et al.*, "An antagonist of integrin alpha-v/beta-3 prevents maturation of blood vessels during embryonic neovascularization," J Cell Science, 108: 2655-2661 (1995);
- Elicieri and Cheresh, "The role of alpha-v integrins during angiogenesis: insights into potential mechanisms of action and clinical development," J Clin Invest, 103: 1227-1230 (1999);
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- Grant *et al.*, "Two different laminin domains mediate the differentiation of human endothelial cells into capillary-like structures in vitro," Cell, 58:933-943 (1989) abstract;
- Guise *et al.*, "Evidence for a causal role of parathyroid hormone-related protein in the pathogenesis of human breast cancer-mediated osteolysis," J Clin Invest, 98: 1544-1549 (1996);
- Gujral *et al.*, "Parathyroid hormone-related protein induces interleukin-8 production by prostate cancer cells via a novel intracrine mechanism not mediated by its classical nuclear localization sequence," Cancer Res, 61: 2282-2288 (2001);
- Hoare *et al.*, "Evaluating the signal transduction mechanism of the parathyroid hormone 1 receptor. Effect of receptor-G-protein interaction on the ligand binding mechanism and receptor conformation," J Biol Chem, 276: 7741-7753 (2001);
- Howe and Juliano, "Regulation of anchorage-dependent signal transduction by protein kinase A and p21-activated kinase," Nat Cell Biol, 2: 593-600 (2000) abstract;
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- Humphries *et al.*, "Investigation of the biological effects of anti-cell adhesive synthetic peptides that inhibit experimental metastasis of B16-F10 murine melanoma cells," J Clin Invest, 81:782-790 (1988);
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- Iwamoto *et al.*, "Changes in parathyroid hormone receptors during chondrocyte cytodifferentiation," J Biol Chem, 269: 17245-17251 (1994);
- Jiang *et al.*, "Expression of parathyroid hormone/parathyroid hormone-related protein receptor in vascular endothelial cells," J Cardiovascular Pharmacol, S142-1444 (1998) abstract;
- Jin et al., "Crystal structure of human parathyroid hormone 1-34 at 0.9-A resolution," J Biol Chem, 275: 27238-27244 (2000);
- Karaplis *et al.*, "Lethal skeletal dysplasia from targeted disruption of the parathyroid hormone-related peptide gene," Genes Dev, 8: 277-289 (1994);
- Kim *et al.*, "Regulation of angiogenesis in vivo by ligation of integrin alpha-5/beta-1 with the central cell-binding domain of fibronection," Am J Pathol, 156:1345-1362 (2000);
- Kim *et al.*, "Regulation of integrin alpha-v/beta-3-mediated endothelial cell migration and angiogenesis by integrin alpha-5/beta-1 and protein kinase A," J Biol Chem, 275: 33920-33928 (2000);
- Kiosses *et al.*, "A role for p21-activated kinase in endothelial cell migration," J Cell Biol, 147: 831-843 (1999);
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- Kumar et al., "Targeting integrins alpha-5/beta-3 and alpha-5/beta-5 for blocking tumor-induced angiogenesis" in Maragoudakis (ed.), <u>Advances in Experimental Medicine and Biology</u>, (Angiogenesis: From the Molecular to Integrative Pharmacology), Kluwer Academic / Plenum Publishers: New York, 476:169-180 (2000);
- Lanske *et al.*, "Ablation of the PTHrP gene or the PTH/PTHrP receptor gene leads to distinct abnormalities in bone development," J Clin Invest, 104: 399-407 (1999);
- Leavesley *et al.*, "Integrin beta-1 and beta-3 mediated endothelial cell migration is triggered through distinct signaling mechanisms," J Cell Biol, 121: 163-170 (1993);

- Maeda et al., "Targeted overexpression of parathyroid hormone-related protein (PTHrP) to vascular smooth muscle in transgenic mice lowers blood pressure and alters vascular contractility," Endocrinology, 140: 1815-1825 (1999);
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- Penta *et al.*, "Del1 induces integrin signaling and angiogenesis by ligation of alpha-v/beta-3," J Biol Chem, 274: 11101-11109 (1999);
- Shimizu *et al.*, "Minimization of parathyroid hormone. Novel amino-terminal parathyroid hormone fragments with enhanced potency in activating the type-1 parathyroid hormone receptor," J Biol Chem, 275: 21836-218343 (2000);
- Sipkins *et al.*, "Detection of tumor angiogenesis in vivo by alpha-v/beta-3 targeted magnetic resonance imaging," Nat Med, 4: 623-626 (1998);
- Stromblad et al., "Suppression of p53 activity and p21WAF1/CIP1 expression by vascular cell integrin alpha-v/beta-3 during angiogenesis," J Clin Invest, 98: 426-433 (1996);
- Takahashi *et al.*, "Ischemia- and cytokine-induced mobilization of bone marrow-derived endothelial progenitor cells for neovascularization," Nat Med, 5:434-438 (1999);
- Terkeltaub *et al.*, "Parathyroid hormone-related proteins is abundant in osteoarthritic cartilage, and the parathyroid hormone-related protein 1-173 isoform is selectively induced by transforming growth factor beta in articular chondrocytes and suppresses generation of extracellular inorganic pyrophosphate," Arthritis Rheum, 41: 2152-64 (1998);
- Varner *et al.*, "Inhibition of angiogenesis and tumor growth by murine 7E3, the parent antibody of C7E3 fab (abciximab; ReoPro)," Angiogenesis, 3:53-60 (1999);
- GenBank Accession No. NM_000315 (PTH);
- GenBank Accession No. NM 002820 (PTHrP); and
- GenBank Accession No NM_008854 (PKA).

The following citations, copies attached, were cited during examination of the parent PCT Application No. PCT/US03/20041 (UCSD-07947):

- Kim *et al.*, "Inhibition of endothelial cell survival and angiogenesis by protein kinase A," J Clin Invest, 110: 933-941 (2002);
- Romano *et al.*, "Latest developments in gene transfer technology: achievements, perspectives, and controversies over therapeutic applications," Stem Cells, 18: 19-39 (2000); and
- Shepard, "Endothelial integrins and angiogenesis: not so simple anymore," J Clin Invest, 110: 913-914 (2002).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 5, 2007

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FORM PTO-1449 (Modified)

Department of Commerce Patent and Trademark Office

Attorney Docket No CSD-08879 Serial No.: 10/518,181

Applicant: Judith A. Varner et al INFORMATION DISCLOSURE STATEMENT BY APPLICANT (37 CFR § 1.98(b)) Filing or 371(c) Date: 09/09/2005 Group Art Unit: 1633 U.S. PATENT DOCUMENTS Examiner Cite Document / Publication / Applicant / Patentee Class Subclass Filing Date Initials Patent Number Issue Date FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS Translation Document **Publication Date** Country / Patent Office Class Subclass Number 2007 Yes No OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) Abou-Samra et al., "Expression cloning of a common receptor for parathyroid hormone and parathyroid hormone-related peptide from rat osteoblast-like cells: a single receptor stimulates intracellular accumulation of both cAMP and inositol trisphosphates and increases intracellular free calcium," Proc Natl Acad Sci USA, 89: 2732-2736 (1992) Amizuka et al., "Parathyroid hormone-related peptide-depleted mice show abnormal epiphyseal cartilage development and altered endochondral 2 bone formation," J Cell Biol, 126: 1611-1623 (1994) 3 Arap et al., "Cancer treatment by targeted drug delivery to tumor vasculature in a mouse model," Science, 279: 377-380 (1998) Ausprunk et al., "Vascularization of normal and neoplastic tissues grafted to the chick chorioallantois. Role of host and preexisting graft blood 4 vessels," Amer J Pathol, 79:597-628 (1975) Bakre et al., "Parathyroid hormone related peptide is a naturally occurring protein kinase A-dependent angiogenesis inhibitor," Nature Med, 8: 5 995-1003 (2002) 6 Boudreau et al., "Suppression of ICE and apoptosis in mammary epithelial cells by extracellular matrix," Science, 267: 891-893 (1995) Brooks et al., "Integrin alpha-v/beta-3 antagonists promote tumor regression by inducing apoptosis of angiogenic blood vessels," Cell, 79: 1157-7 1164 (1994) abstract 8 Brooks et al., "Requirement of vascular integrin alpha-v/beta-3 for angiogenesis," Science, 264: 569-571 (1994) 9 Bukoski et al., "Vascular actions of the calcium-regulating hormones," Semin Nephrol, 15: 536-549 (1995) abstract 10 Carmeliet and Jain, "Angiogenesis in cancer and disease," Nature, 407: 249-257 (2000) Carron et al., "A peptidomimetic antagonist of the integrin alpha-v/beta-3 inhibits Leydig cell tumor growth and the development of 11 hypercalcemia of malignancy," Cancer Res, 58: 1930-1955 (1998) Christofidou-Solomidou et al., "Expression and function of endothelial cell alpha-v integrin receptors in wound-induced human angiogenesis in 12 human skin/SCID mice chimeras," Am J Pathol, 151: 975-983 (1997) 13 Clark et al., "Transient functional expression of alpha-v/beta-3 on vascular cells during wound repair," Am J Pathol, 148: 1407-1421 (1996) Clegg et al., "Inhibition of intracellular cAMP-dependent protein kinase using mutant genes of the regulatory type I subunit," J Biol Chem, 262: 14 13111-13119 (1987) Dormond et al., "NSAIDs inhibit alpha-v/beta-3 integrin-mediated and Cdc42/Rac-dependent endothelial-cell spreading, migration and 15 angiogenesis," Nat Med, 7: 1041-1047 (2001) Drake et al., "An antagonist of integrin alpha-v/beta-3 prevents maturation of blood vessels during embryonic neovascularization," J Cell 16 Science, 108: 2655-2661 (1995) Elicieri and Cheresh, "The role of alpha-v integrins during angiogenesis: insights into potential mechanisms of action and clinical development," 17 J Clin Invest, 103: 1227-1230 (1999) 18 Friedlander et al., "Definition of two angiogenic pathways by distinct alpha-v integrins," Science, 270: 1500-1502 (1995) Friedlander et al., "Involvement of integrins alpha-v/beta-3 and alpha-v/beta-5 in ocular neovascular diseases," Proc Natl Acad Sci USA, 93: 19 9764-9769 (1996) Grant et al., "Two different laminin domains mediate the differentiation of human endothelial cells into capillary-like structures in vitro," Cell, 20 58:933-943 (1989) abstract Guise et al., "Evidence for a causal role of parathyroid hormone-related protein in the pathogenesis of human breast cancer-mediated osteolysis," 21 J Clin Invest, 98: 1544-1549 (1996) Gujral et al., "Parathyroid hormone-related protein induces interleukin-8 production by prostate cancer cells via a novel intracrine mechanism not 22 mediated by its classical nuclear localization sequence," Cancer Res, 61: 2282-2288 (2001) Hoare et al., "Evaluating the signal transduction mechanism of the parathyroid hormone 1 receptor. Effect of receptor-G-protein interaction on 23 the ligand binding mechanism and receptor conformation," J Biol Chem, 276: 7741-7753 (2001) Howe and Juliano, "Regulation of anchorage-dependent signal transduction by protein kinase A and p21-activated kinase," Nat Cell Biol, 2: 593-24 600 (2000) abstract Humphries et al., A synthetic peptide from fibronectin inhibits experimental metastasis of murine melanoma cells," Science, 233:467-470 (1986) 25 Examiner:

FORM PTO-1449 (Modified)

U.s. Department of Commerce Patent and Trademark Office

Attorney Docket No. CSD-08879 Serial No.: 10/518,181

Applicant: Judith A. Varner et al.

Filing or 371(c) Date: 09/09/2005

Group Art Unit: 1633

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (37 CFR § 1.98(b))

ST CITES	1.98(b))	Filing or 371(c) Date: 09/09/2005 Group Art Unit: 1633
		OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)
	26	Humphries et al., "Investigation of the biological effects of anti-cell adhesive synthetic peptides that inhibit experimental metastasis of B16-F10 murine melanoma cells," J Clin Invest, 81:782-790 (1988)
	27	Isner and Asahara, "Angiogenesis and vasculogenesis as therapeutic strategies for postnatal neovascularization," J Clin Invest, 103:1231-1236 (1999)
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	30	Jin et al., "Crystal structure of human parathyroid hormone 1-34 at 0.9-A resolution," J Biol Chem, 275: 27238-27244 (2000)
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	38	Lanske et al., "Ablation of the PTHrP gene or the PTH/PTHrP receptor gene leads to distinct abnormalities in bone development," J Clin Invest, 104: 399-407 (1999)
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	53	Kim et al., "Inhibition of endothelial cell survival and angiogenesis by protein kinase A," J Clin Invest, 110: 933-941 (2002)
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Examiner:		Date Considered:

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